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November 15, 2024

Committee on Health, Education, Labor & Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, D.C. 20510
Attn: Chairman Bernie Sanders
Ranking Member Bill Cassidy

Re: Well-Documented Clinical Data Fraud Endangering Cancer Patients – Refused to be Addressed by **Assertio Holdings, Inc. (NASDAQ: ASRT)**

Dear Senators of the Committee:

The Buxton Helmsley Group, Inc. ("**BHG**" or "**we**") addresses the Senate in relation to Assertio Holdings, Inc. ("**Assertio**") (NASDAQ: ASRT), after **Assertio's Chairman and its M.D. oncologist board member have just resigned.** Those resignations were announced just one business day following BHG's public release of an exposé (linked below) regarding well-documented clinical data fraud at Assertio subsidiary Spectrum Pharmaceuticals, Inc. ("**Spectrum**"), with **multiple former executives-turned-whistleblowers possessing extensive non-public evidence, *including real, untampered clinical data*.** BHG also engaged an outside law firm to conduct an independent investigation into the corroborating whistleblower allegations and their extensive non-public supporting evidence/data.

Right now, Rolvedon[1] is being dosed to cancer patients (paid for under a unique "J-Code" (J1449), and is thereby being purchased by the U.S. Government, since 2023), putting those patients' health at risk as a result of the evident clinical data fraud—there is no excuse. For example, we enclose (below) an e-mail from an employee of Spectrum to its executives, stating:

> *"**I'm trying to understand the below. I've never 'deleted [Adverse Events]' from a database. I need to understand the history and decision making here.** During the ROLONTIS BLA BIMO inspection, I will be scrutinized for any Note To File (NTF) surroundings deletion of [Adverse Events]."*

[1] Rolvedon (initially investigated as "Rolontis") is a biologic cancer treatment, approved in 2022 by the FDA despite the undetected clinical data fraud, initially marketed under the brand name "Rolontis". **Three BLA submissions (from 2018 to 2022) were required for Rolontis, given such problematic submissions to the FDA, as thoroughly discussed within the first-linked press release. It can be gleaned from public records that the same core population data was submitted for each of the three BLA submissions.** Shedding light on why Assertio's leadership has continued its "head in the sand" approach over these matters, Rolvedon/Rolontis is Assertio's biggest revenue-generator, bringing in approximately $60mm per year, or approximately 50% of Assertio's overall revenues.

Assertio's leadership claims that a "thorough investigation" of the corroborating whistleblower allegations was undertaken. However, Assertio never spoke to the whistleblowers they claim to have investigated the corroborating allegations of, and never obtained the extensive non-public evidence in the possession of those whistleblowers. Despite such a sham investigation (at best), Assertio's board of directors and management claim "no merit" to the allegations of those whistleblowers.

Assertio's leadership stated on their November 11, 2024 earnings call that they will never again address these matters (as if they ever addressed them to begin with), despite their clear sham investigation (a convenient "head in the sand" approach, to continue raking in profits at the same time of endangering cancer patients). **Such a refusal to address these matters was communicated on the earnings call, in particular, by Assertio CEO Brendan O'Grady, who is also a member of the board of directors.**

It is clear now that the only way this well-documented clinical data fraud endangering cancer patients will be addressed is by action of the Senate. We believe it is more than required that the Committee on Health, Education, Labor & Pensions hold a hearing that will *require* Assertio's leadership to hear from these multiple former executives-turned-whistleblowers (possessing immense non-public evidence as to this egregious instance of clinical data fraud), to further unravel this egregious, well-documented scheme that the Assertio board of directors is now, clear to us, attempting to turn a blind eye to. We hope such a hearing will compel the U.S. HHS, FDA, and SEC to take *immediate* action here, as cancer patients and investors are—again—in imminent danger. A firm example needs to be made by the Senate out of Assertio's board of directors and management.

Grant Thornton LLP (Assertio's auditor), even after BHG has raised these matters directly to them *multiple times*, also apparently continues to stand by Assertio's perpetuated misconduct; that is, even after—on Monday, November 11, 2024—BHG publicly released that below-enclosed e-mail from a Spectrum employee, evidencing their having been asked to delete adverse events from clinical data, and with such a clear sham investigation having been conducted by Assertio's board of directors, if any investigation at all. Such requests to delete adverse events from clinical data did not end with that employee either. As is also part of the "well-documented" nature of this clinical data fraud scheme, there were notes to clinical data files that adverse events were "deleted at sponsor's request" (clinical trial sites had documented in the notes section that they had deleted serious adverse events at the request of Spectrum, now a wholly-owned subsidiary of Assertio). The Assertio Board's investigation failures, not to mention the underlying well-documented clinical data fraud, implicate stark failures (by Assertio, Grant Thornton's audit client) to uphold Principles 1 and 2 of the COSO Framework. Yet, Grant Thornton has *still* not resigned.[2]

[2] Ernst & Young acted correctly when they recently resigned from their engagement as the auditor of Super Micro Computer, Inc. (NYSE: SMCI), *before* matters became public indicating why Ernst & Young believed SMCI's leadership was not upholding Principles 1 and 2 of the COSO Framework. Here, it is now *entirely public* that Assertio's leadership has failed to even speak with, let alone obtain all evidence from, multiple former executives-turned-whistleblowers with extensive troves of evidence supporting their corroborating allegations of clinical data fraud. That is far from a commitment to ethical and lawful conduct (starkly violating Principle 1 of the COSO Framework), and a board of directors independent from management would *never* have concluded an investigation of such serious allegations of fraud by multiple executives-turned whistleblowers without having spoken with them, and without collecting the evidence in the possession of those whistleblowers (starkly violating Principle 2 of the COSO Framework). It goes without saying that, where there is fraud, whistleblowers often have evidence that has already been hidden, covered up, or deleted, as was the case here. Grant Thornton has an obligation to resign from such an audit client immediately, given such failures, and *even public* defiance, when it comes to upholding Principles 1 and 2 of the COSO Framework.

* * *

Rather than restating the details of this egregious, unaddressed misconduct occurring at Assertio, how BHG learned of it, and how we connected with the multiple former executives-turned-whistleblowers, we point the Senate to **BHG's press release immediately preceding the announcement of Assertio's Chairman (and its M.D. oncologist board member, Dr. Jeffrey Vacirca, M.D.) resigning, in addition to BHG's follow-on press release days later, within which BHG began to release evidence of the clinical data fraud (including a clinical trial site audit report citing "Major" clinical trial data discrepancies at MD Anderson Cancer Center, whose data was used by Spectrum as part of regulatory submissions to the FDA):**

- Press Release by BHG Exposing Matters (Friday, November 8, 2024): https://www.businesswire.com/news/home/20241107257609/en/
- Press Release by BHG Beginning to Release Evidence (Monday, November 11, 2024): https://www.businesswire.com/news/home/20241111117591/en/

As noted within the first-linked press release, the "First Spectrum Whistleblower" is Spectrum's former Senior Counsel for Global Research and Development, **who *refused to sign off on the initial Rolontis Biologic License Application with the FDA, given her knowledge the submission contained tampered, fraudulent clinical data*. This whistleblower has been offered effective "hush money" by Assertio, under the creative guise of a "settlement" (as the Senate knows, many arguable "hush money" agreements are made under the guise of some purpose that could be legitimate under other circumstances—the unusual terms and circumstances of those offers establish the *real* intent, just as in this case).**

As further noted in the November 8 press release, the "Second Spectrum Whistleblower" is an Ivy League-educated physician who oversaw clinical trials at Spectrum. **Interestingly, this second former executive-turned-whistleblower was kept on the payroll for *over a year* after being "terminated." Such continued pay after "termination" does not "just happen"—another clear attempt of "hush money" under these circumstances of terminating a protected whistleblower who spoke up about the fraudulent conduct she was witnessing at Spectrum.**

* * *

In the words of the whistleblowers, cancer patients deserve respect. After generously giving their bodies to science, cancer patients trust corporations and healthcare institutions will accurately report their clinical trial data, and with integrity. Years ago, the FDA set expectations through its guidance on Data Integrity and Compliance for the Drug Manufacturing (cGMPs). However, to date, the FDA has not addressed pre-clinical and clinical research data (cGCPs) that directly speaks on whether or not a medical product is worthy of the FDA's approval or clearance. The FDA needs to implement programs and technical systems designed to protect the integrity and accuracy of clinical data received in regulatory submissions, case in point here. Compliance in the medical world is so critical it requires both *trust* and *verification* technologically. Such would build efficiency into the compliance process.

In closing, we believe it is in the interest of public safety for the Senate to hold a hearing concerning these matters, where—most importantly—the Senate may question Assertio's board of directors and management, at the same time of the Senate hearing from the multiple former executives-turned-whistleblowers Assertio's leadership claims to have "thoroughly investigated" the allegations of, despite never having spoken to those brave whistleblowers, and never having collected the extensive evidence in the possession of those whistleblowers. We believe such a hearing by the Senate is required to ensure that the publicity compels

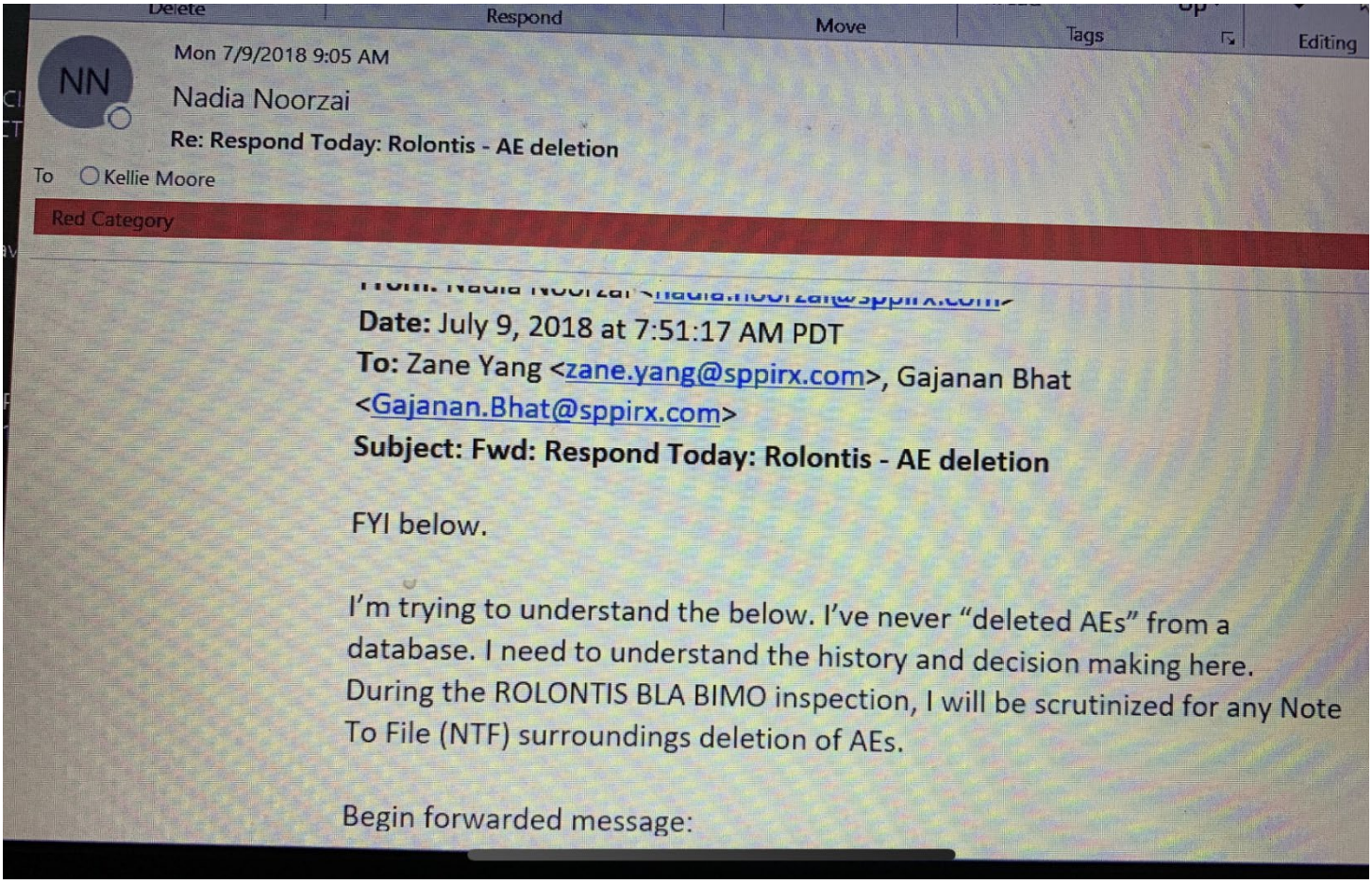
immediate action of the U.S. FDA, HHS, and SEC. Assertio's leadership is now absolutely hopelessly conflicted in any investigation of these matters they have so neglected (there is no "re-opening" their sham "investigation," now at this point), leaving the clear need for regulatory investigation and intervention. BHG has filed a whistleblower report with the U.S. SEC, but has not yet heard from the agency.

We respectfully hope to hear from the Committee shortly.

Very Truly Yours,

Alexander E. Parker
Senior Managing Director
The Buxton Helmsley Group, Inc.

Cc: U.S. Senate Committee on Finance – All Members
Heather L. Mason (Chair, Assertio Holdings, Inc.)
William T. Mckee (Director, Assertio Holdings, Inc.)
Sravan K. Emany (Director, Assertio Holdings, Inc.)
Sigurd C. Kirk (Director, Assertio Holdings, Inc.)
David Stark (Director, Assertio Holdings, Inc.)
Brendan P. O'Grady (Director and Chief Executive Officer, Assertio Holdings, Inc.)
Ajay Patel (Chief Financial Officer, Assertio Holdings, Inc.)
Matthew Kreps (Investor Relations Officer, Assertio Holdings, Inc.)


Delete
Respond
Move
Tags
Editing
NN
Mon 7/9/2018 9:05 AM
Nadia Noorzai
Re: Respond Today: Rolontis - AE deletion
To Kellie Moore
Red Category
From: Nadia Noorzai <nadia.noorzai@sppirx.com>
Date: July 9, 2018 at 7:51:17 AM PDT
To: Zane Yang <zane.yang@sppirx.com>, Gajanan Bhat <Gajanan.Bhat@sppirx.com>
Subject: Fwd: Respond Today: Rolontis - AE deletion
FYI below.
I'm trying to understand the below. I've never "deleted AEs" from a database. I need to understand the history and decision making here. During the ROLONTIS BLA BIMO inspection, I will be scrutinized for any Note To File (NTF) surroundings deletion of AEs.
Begin forwarded message: